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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,885	08/27/2001	Susan Niemiec	J&J-2047	5256

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AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,885

Applicant(s)

Niemiec

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 14, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13, and 24-33 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 9, 13, 28, and 29 is/are rejected.
- 7) ☒ Claim(s) 2-4, 6-8, 24-27, and 30-33 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 6) ☐ Other: _____

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DETAILED ACTION

The request for the extension of time and amendment dated 4-14-03 are acknowledged.

Pending claims are 1-9, 13 and 24-33.

Claim Objections

Claims 2-4, 6-8, 24-27 and 30-33 depend from canceled claim 10 and therefore, these claims are not treated on merits.

Claims included in the prosecution are 1, 5, 9, 13 and 28-29.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenk (5,169,637).

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Lenk discloses multilamellar liposomes containing polyvinylpyrrolidone (PVP) (Table III on col. 17). The intended use has no patentable significance in composition claims.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1 and 5 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Schmidt (5,817,334).

Schmidt discloses liposomes containing PVP (note col. 7, lines 11-61 and Table 1 on col. 11. As pointed out above, the intended use has no patentable significance in composition claims.

This application is a CIP of 09/320,894. The 102 (b) rejection will be reconsidered, once the support for the claims is documented in the parent case.

4. Claim 9 remains rejected under 35 U.S.C. 102(b) or (a) as being anticipated by WO 96/31194.

WO 96 discloses skin care compositions containing non-phospholipid liposomes. The compositions containing glyceryl distearate (dual chain lipid), glyceryl monostearate (single-chain lipid), cholesterol, polysorbate 80 (detergent) and steareth-10 (conditioning polymer). The compositions also include cyclomethicone, conditioning polymer (note pages 23-24, 32-33).

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Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that claim 9 (not claim 24 as indicated by applicant on page 6 of the response) to recite the molecular weight of at least 1000 and therefore, the reference is no longer applicable. This argument is not found to be persuasive since the reference teaches the polymer, stearth 10 and this polymer is a polyoxyethylene derivative of stearic acid and therefore, has a molecular weight of more than 1000 as the instant claim would require. The examiner cites US 6,245,713 in this context (see col. 59, lines 62-65). The reference meets the requirements of instant claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenk or Schmidt cited above.

Neither Lenk nor Schmidt teach the molecular weights of polyvinylpyrrolidone. However, in the absence of showing the criticality, the use of polyvinylpyrrolidone with

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different molecular weights to obtain the best possible results is deemed to be obvious to one of ordinary skill in the art.

7. Claims 1, 5, 13 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delrieu (5,962,015) or Brookasomes, or Hart (5,328,628) in view of Burke (5,562,912) or vice versa (Burke in view of Delrieu or Brookasomes or Hart).

As pointed out in the previous action, Delrieu discloses liposome formulations containing lecithin (dual chain lipid) and a polymer, quaternized polysaccharide (note the abstract, col. 2, line 55 through col. 5, line 53; Examples and claims). The liposomes also include hyaluronic acid (col. 7, line 34). The formulations are for cleansing, beautifying and conditioning or protecting the body surface (note col. 7, lines 59-62).

As also pointed out before, Brookasome brochure shows that phospholipid liposomes containing hyaluronate is commercially available (note pages 6 and 7). The compositions are used as cosmetic compositions and meant for skin.

Hart teaches shower compositions containing liposomes. The liposomes are made from either phospholipids or non-phospholipids. The compositions further contain a surfactant (detergent) (note the abstract, columns 5-13 and Examples).

What is lacking in Delrieu, Brookasomes or Hart is the inclusion of polyvinylpyrrolidone in the formulations.

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Burke while disclosing skin cleanser compositions teaches that polyvinylpyrrolidone when included in the skin cleanser compositions, improves the foam character, after feel and rinsability (note the abstract and col. 3, lines 33-35).

The inclusion of polyvinylpyrrolidone in the liposome compositions taught by Delrieu, Brookasomes or Hart would have been obvious to one of ordinary skill in the art since Burke teaches that this compound when included in the skin compositions, improves the foam character, after feel and rinsability. Alternately the use of liposomes in the compositions of Burke would have been obvious to one of ordinary skill in the art because Brookasomes teaches that in their liposomal form, cosmetic agents exhibit better stability, penetration and efficacy a lower usage levels (page 3, top two lines) and because both Delrieu and Hart teach that liposomes are carriers for active agents in skin cosmetics preparations.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant point out Example 8 in the specification and argue that after three washings, the fluorescent signal was gone indicating that PVP alone, not encapsulated in liposomes, is not effective in retaining PVP on or in the hair fibers over several washings as compared to PVP in liposomes. This argument is not found to be persuasive since contrary to unexpected nature of the results argued by applicant, the result is to be expected since liposomes are known 'sustained release agents' meaning that the active agent is released

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from the liposomes in a sustained way. Therefore, the presence of fluorescence on the hair in the in the experiment using liposome encapsulated PVP is to be expected and not unexpected in nature.

8. Claims 1, 5, 9, 13 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/31194 in view of Burke (5,562,912), both cited above, or vice versa (Burke in view of WO 96/31194).

As pointed out above, WO 96 discloses skin care compositions containing non-phospholipid liposomes (niosomes). The compositions containing glyceryl distearate (dual chain lipid), glyceryl monostearate (single-chain lipid), cholesterol, polysorbate 80 (detergent) and steareth-10 (conditioning polymer). The compositions also include cyclomethicone, conditioning polymer (note pages 23-24, 32-33). Besides niosomes, WO also teaches lecithin (dual chain lipid) containing liposomes. What is lacking in WO is the teaching of the inclusion of polyvinylpyrrolidone.

As discussed above, Burke while disclosing skin cleanser compositions teaches that polyvinylpyrrolidone when included in the skin cleanser compositions, improves the foam character, after feel and rinsability (note the abstract and col. 3, lines 33-35).

The inclusion of polyvinylpyrrolidone in the liposome compositions taught by WO would have been obvious to one of ordinary skill in the art since Burke teaches that this compound when included in the skin compositions, improves the foam character, after feel

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and rinsability. Alternately the use of liposomes in the compositions of Burke would have been obvious to one of ordinary skill in the art, with the expectation of obtaining similar results, because WO shows that polymers can be encapsulated in skin care compositions. The criticality of the 'molecular weights' now introduced through new claims 28 and 29 is not readily apparent to the examiner.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again pertain to the unexpected results. These have been addressed above. Furthermore, instant specification does not show any experimental data obtained using liposomes prepared by using phospholipids.

In view of applicant's amendments, the rejection of claims over Brookasomes or Delrieu cited above, in view of WO 96/31194 or vice versa is withdrawn.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

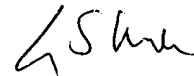
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility

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that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

June 19, 2003